Probabilistic risk assessment and benefit-cost analysis

Workshop: Advancing Quantitative Analysis in Human Health Assessments through Probabilistic Methods

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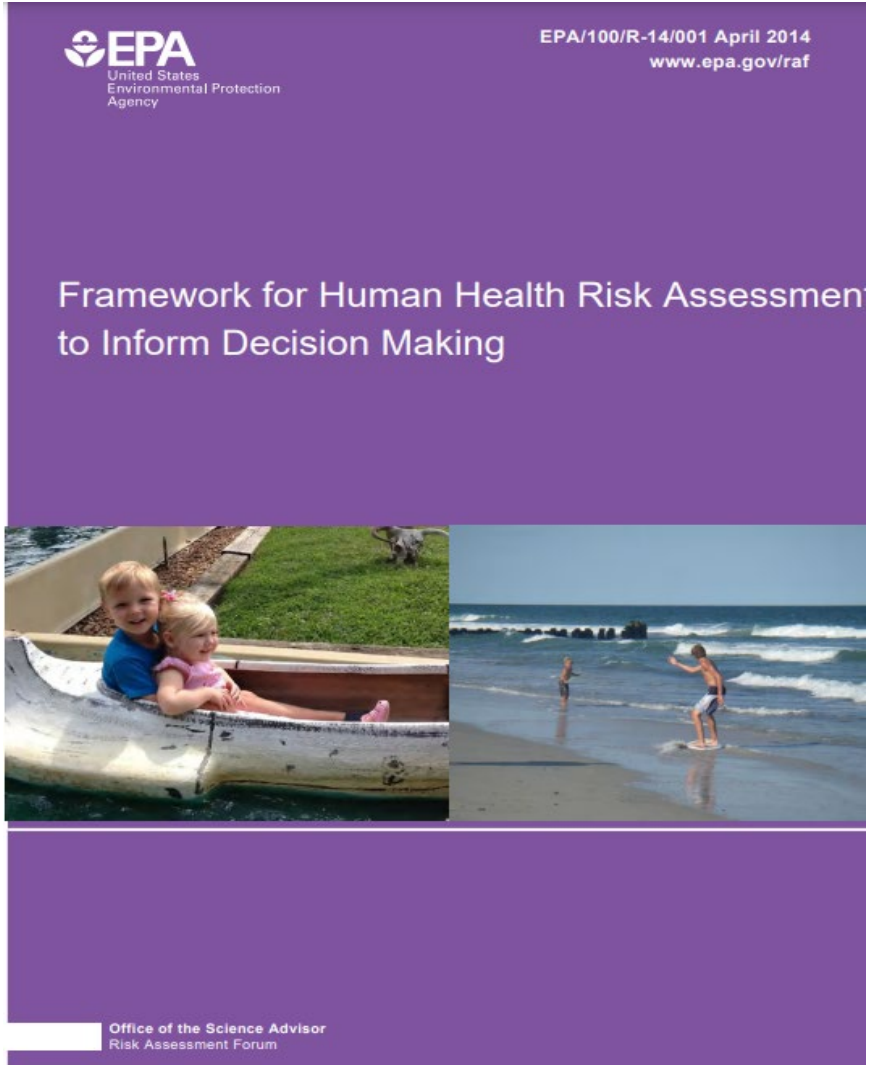
The opinions expressed in this presentation are mine and do not necessarily represent official positions of EPA of the federal government

With this framework document, EPA introduces the concept of "fit for purpose" to characterize risk assessments that are designed to maximize the utility of risk assessments for their intended purpose in Agency decision making

Benefit-cost analysis (BCA) is one of these purposes.

Current practice for most non-cancer assessments does not meet this purpose.



Credit: Scott Suchman for The Washington Post/food styling by Lisa Cherkasky for The Washington Post

Why benefits analysis? The Law

- Clean Air Act (CAA)
- Comprehensive Environ
  and Liability Act (CERCL
- Federal Insecticide, Fun
- Federal Water Pollution Co Act (CWA)
- Safe Drinking Water Act (SDWA)
- Resource Conservation and Recover Act (RCRA)
- Toxic Substances Control Act (TSCA)

EPA must publish, seek comment on, and use…an analysis of…quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record that such benefits are likely to occur…

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- Resource Conservation and Recover Act (RCRA)
- Toxic Substances Control Act (TSCA), as amended in 2016

In proposing or promulgating a rule…the Administrator shall consider and publish a statement…with respect to…the reasonably ascertainable economic consequences, including consideration of…the costs and benefits of the proposed and final regulatory action considered…

Why benefit-cost analysis?

Executive orders require it for major regulations including 12866, 13563, and Modernizing Regulatory Review (2023)

[Agencies must conduct] an assessment, including the underlying analysis of benefits anticipated from the regulatory action (such as…the enhancement of health and safety…) together with, to the extent feasible a quantification of those benefits…

Important public information for comment (on proposed rules) and on consequences of regulation

Frontiers of BCA

FACT SHEET: Biden-Harris Administration Announces New Initiative to Advance the Frontiers of Benefit-Cost Analysis and Strengthen Government Decision Making

The report identifies [5] specific areas where further research could significantly benefit government decision making by helping agencies improve analysis of the effects of their actions. (December 2023)

Chapter 1: Non-Fatal Health Effects

Assessing the incidence of such health effects is critical…

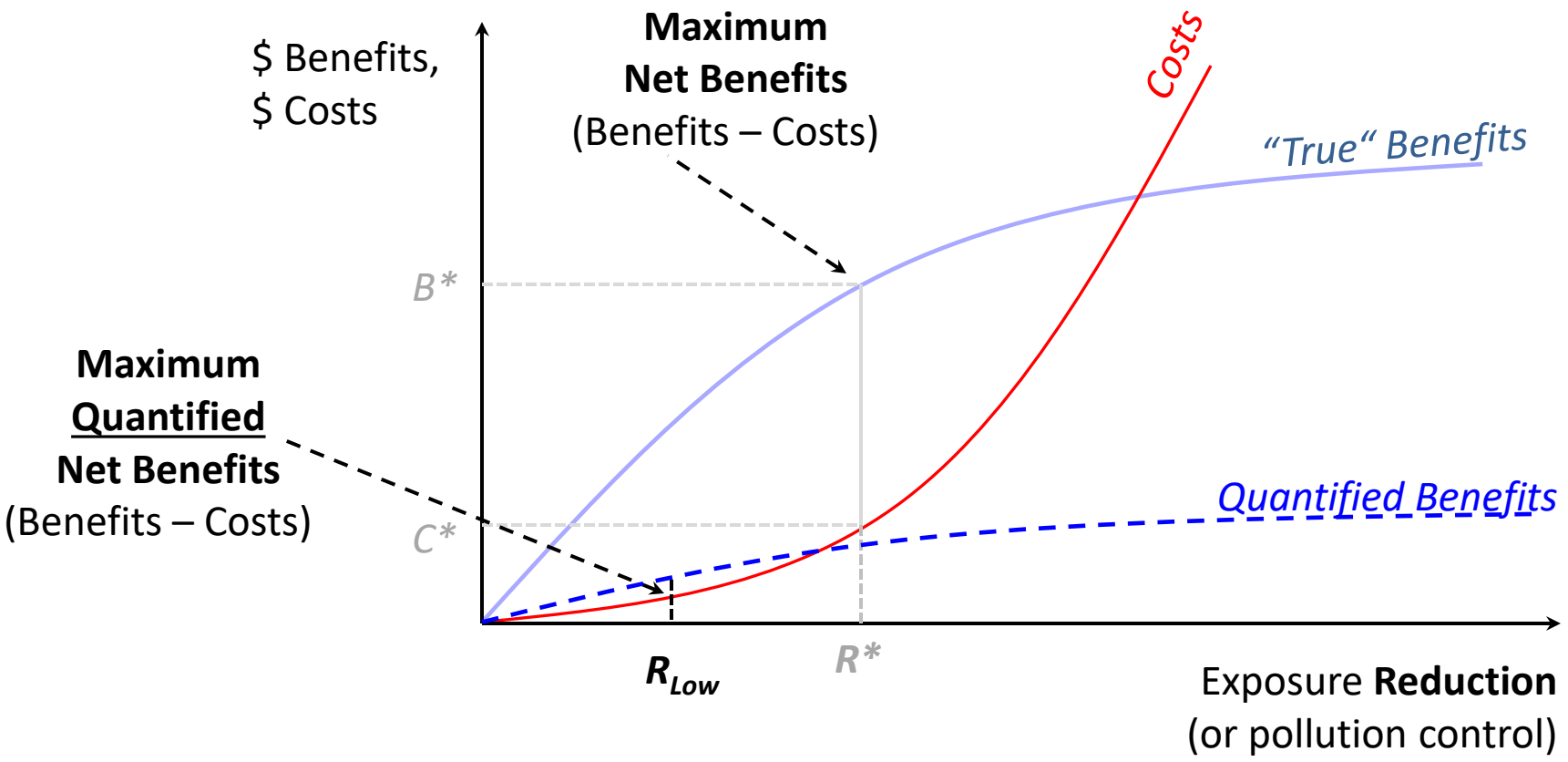
Box 1. Non-Fatal Health Effects: Key Data Gap Examples.

- Dose-response functions for non-cancer health effects at low doses
- Biomonitoring data for quantifying exposures

Second report to be released fall 2024 with more details and next steps for non-fatal health effects.

https://www.whitehouse.gov/wp-content/uploads/2023/12/FINAL-SFBCA-Annual-Report-2023.pdf

Comparing Benefits and Costs



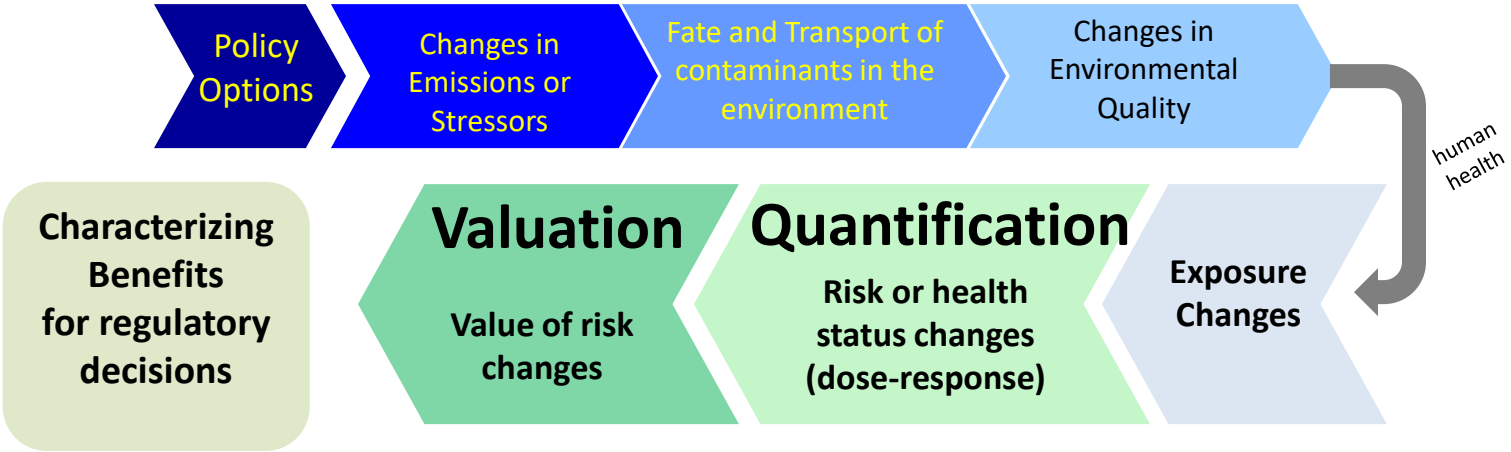
A few points on economic benefits analysis

- Benefit cost analysis (BCA) provides information on **tradeoffs**: the value (in $ terms) of the risk reduction vs. cost of achieving it.
  - Requires our **best quantitative estimate of expected benefits** and costs
- Health endpoints must be economically meaningful (e.g., defined health condition)
- BCA is endpoint(s)-specific: a complete benefits analysis quantifies all such health outcomes associated with exposure reduction.
- Need benefits analysis for many options relative to the baseline
  - Must be able to predict changes in risk and monetized benefits across a range of exposures
- Difficult to effectively characterize non-quantified benefits.

Benefits Estimate	10 µg/m³ annual & 35 µg/m³ 24-hour	10 µg/m³ annual & 30 µg/m³ 24-hou
Economic value of avoided $PM_{2.5}$-related morbidities and pre estimate from Pope (2019)		
3% discount rate	$32 + B	$40 + B

Benefits Analysis and Risk Assessment

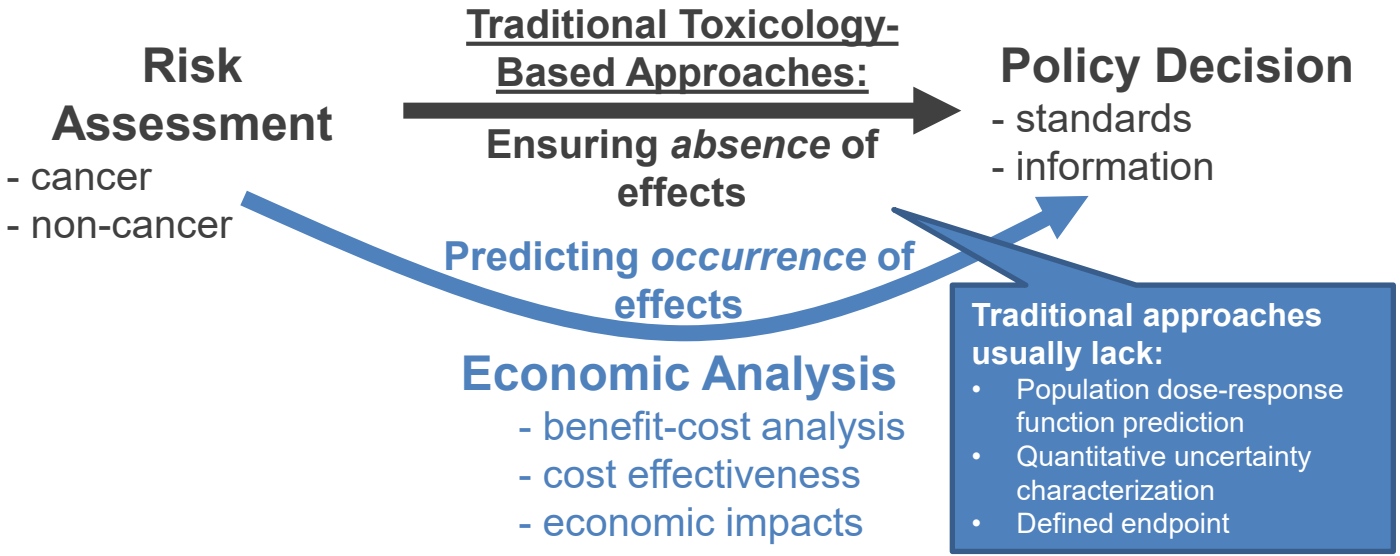
Typical chain of analyses for benefits analysis



Economic analysis requires us

- quantify the changes in risk (or expected cases averted)
- estimate the economic value of those changes in risk (or expected cases averted)

An Economist's View of Toxicology and Risk Assessment

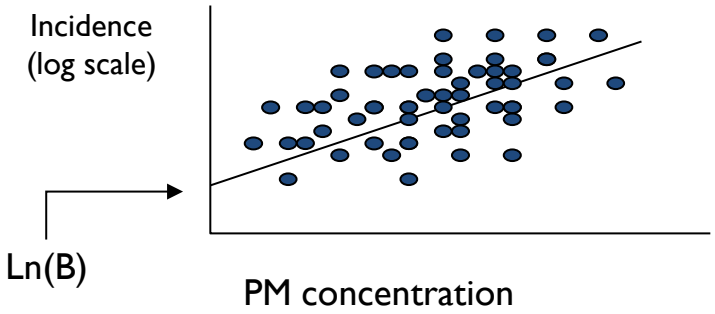


With thanks to Wiehsueh Chiu for improvements to the original figure

Quantifying with human data

- Risk assessments may be based on epidemiological data
  - In the species of interest (humans)
  - Concentration or dose-response functions across range of exposures
  - Often in the relevant exposure range
  - Health endpoints are more likely to be relevant for benefits analysis
- Challenges remain
  - fewer observations in low dose range increases uncertainty
  - different studies may use different biomarkers (e.g., blood lead v. bone lead)
  - timing of effects from changes in the exposure

Epidemiology Study



Examples

- Ozone (O3)
- Particulate matter (PM)
- Lead (Pb) – IQ, cardiovascular
- PFAS chemicals – cardiovascular, birthweight
- Disinfection byproducts

Cancer RA and benefits

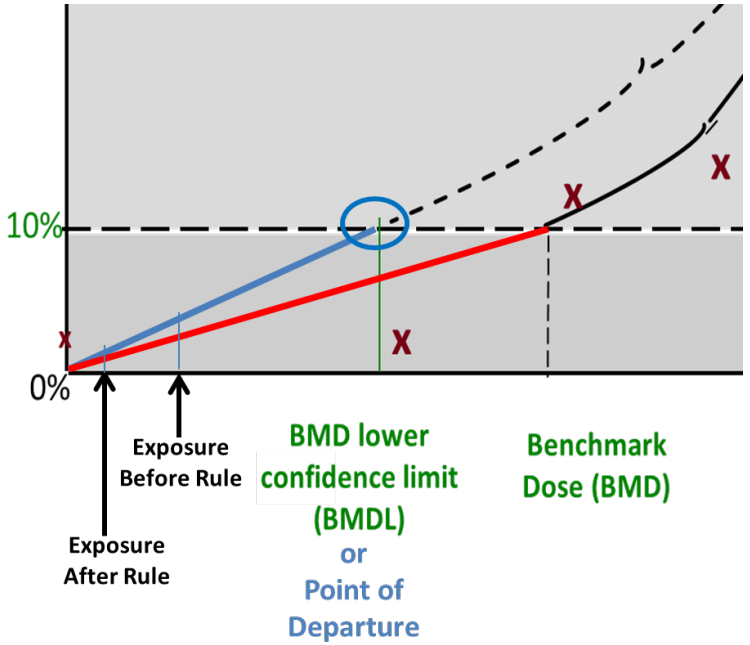
For linear extrapolation use BMD for a central dose-response function

- BMDL extrapolation overstates risk changes
- Apply to population to estimate number of expected cancer cases reduced.

Other considerations for economics

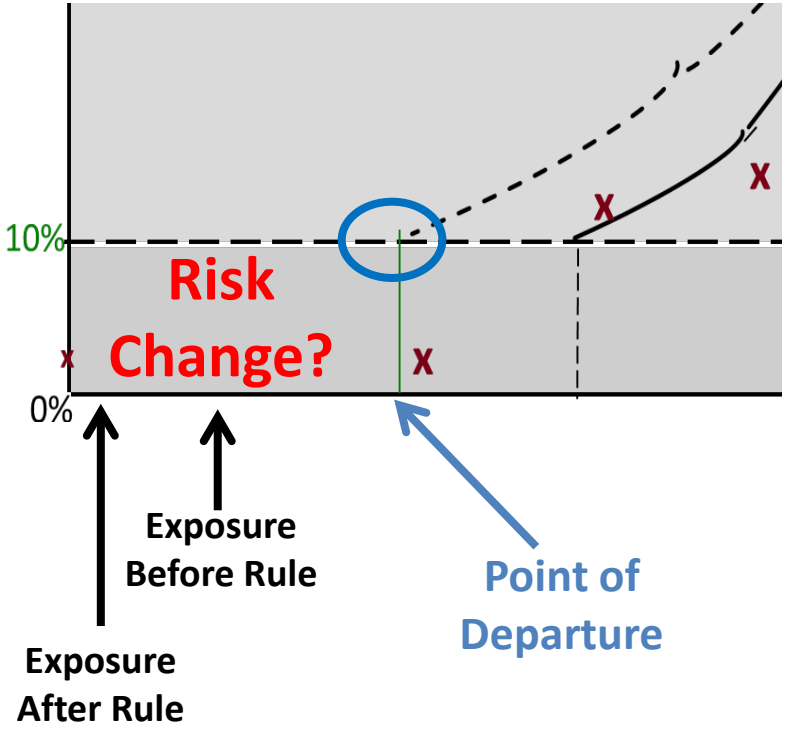
1. Timing of cancer cases – latency/cessation lag
2. Adjust for less-than-lifetime exposures
3. Account for cancer survival (varies by cancer type)

What to do for non-linear/threshold MOA?

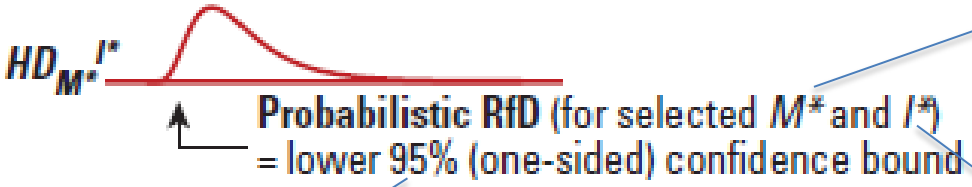


Non-cancer RA and benefits

- Without dose-response the risk change is unknown, and averted cases and benefits cannot be quantified
- Costs are quantified
- Cannot directly assess tradeoffs
  - Quantified benefits = zero and negative quantified net benefits
  - Qualitative descriptions
  - Breakeven analysis if $/case is well-known



Application of HDMI to economic analysis (EA) may require fewer science policy decisions than probabilistic reference dose (pRfD)



What magnitude /severity (M*)?

Must be decided for both pRfD and EA applications

What uncertainty level (e.g., 95%)**?**

pRfD: science policy decision

EA: use central estimate, but characterize uncertainty bounds

What is the target incidence (I*)?

pRfD: science policy decision

EA: no target. Uses the set of risk-specific doses

Can benefits analysis use tox endpoints?

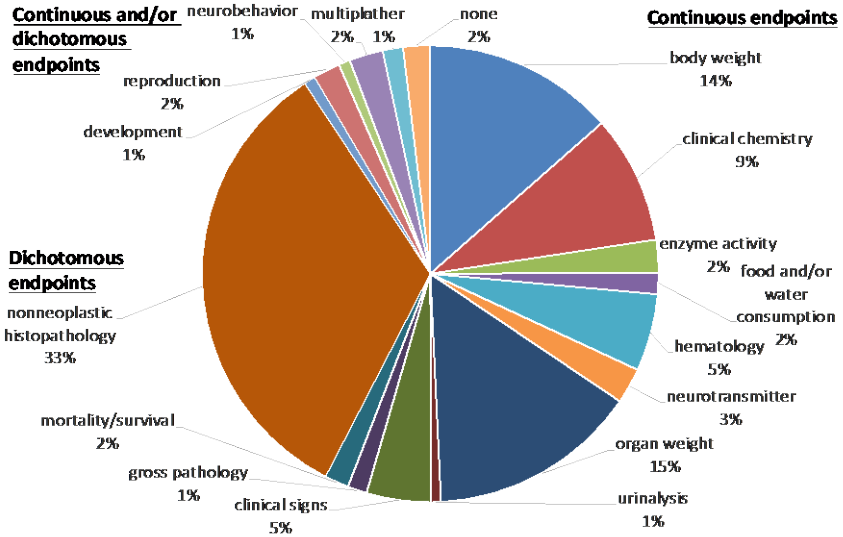
Chiu et al 2018

- 1464 RfDs and endpoints
- 608 Chemicals (351 with multiple RfDs or endpoints)

Perhaps ~100 seem to align clearly with human endpoints for valuation

- Birth weight (25)
- Mortality (25)
- Fetal loss (6)
- Fertility (14)
- Cardiovascular (6)

Requires additional analysis and research, and perhaps science policy decisions.



Chiu et al. (2018) https://doi.org/10.1289/EHP3368

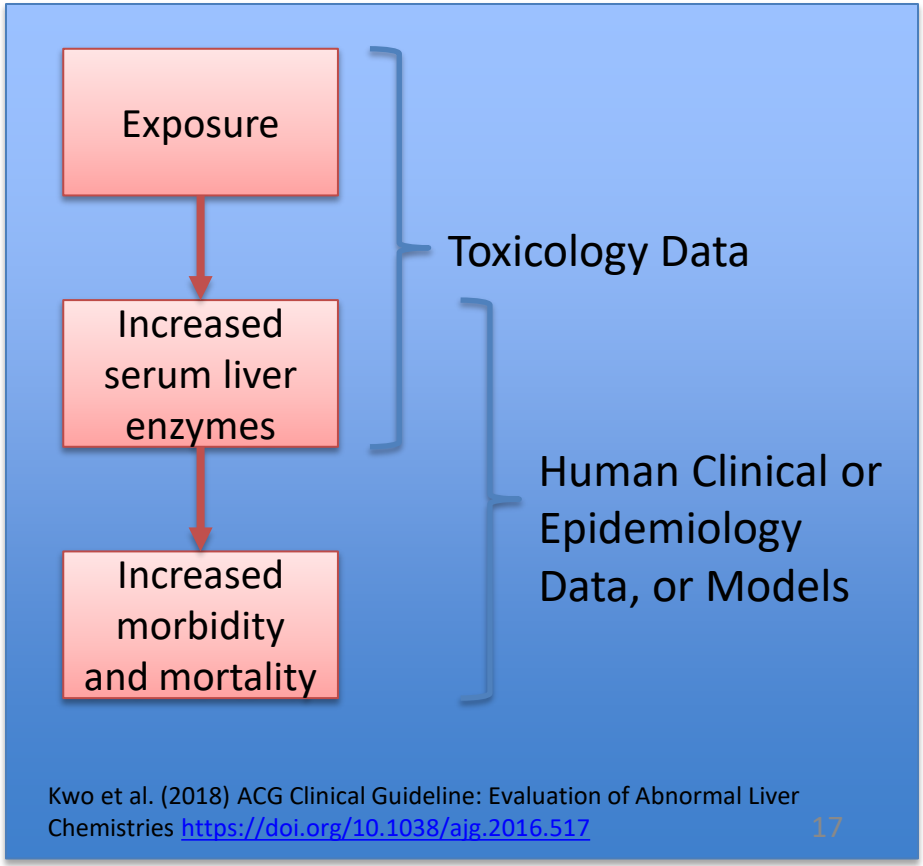
Integrating tox and human data for benefits analysis

Identify intermediate endpoints to connect exposure to economically meaningful health effects

- Exposure → serum levels → disease

Additional analysis to

- Identify are these common intermediate outcomes
- Estimated economic values for associated human health endpoints



Adapted from presentation by Chiu 2024

Summary

- Current assessments often cannot provide information necessary for benefits analysis; probabilistic risk assessments are essential.
- As a result, quantified benefits for many non-cancer effects are zero, which is unlikely to be our best quantitative estimate.
- The WHO/IPCS approach can provide quantitative estimates. The focus thus far has been on probabilistic reference doses. Additional applications/case studies would be useful.
- Application for benefits analysis does not necessarily require same science policy decisions as a probabilistic RfD/RfC.
- Applicability of tox endpoints may be the most challenging technical issue.
- There are many (many!) valuation challenges that I didn't cover here. Addressing these should be informed by advances in risk assessment.

Thank you!

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